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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,972	DOUCETTE-STAMM ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,17-20 and 32-34* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☒ Claim(s) *33 and 34* is/are allowed.

6)☒ Claim(s) *1-13 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on 3/21/06 is acknowledged and entered.

Status of claims

2. Claims 5, 9, 10, 32, 33, and 34 have been amended.

Claims 14-16 and 21-31 have been previously canceled.

Claims 1-13, 17-20 and 32-34 are pending.

Claims 1-13 and 32-34 are under examination.

Claims 17-20 are withdrawn as being drawn to a nonelected invention.

Sequence Rule Non-compliance withdrawn

3. In view of submission of new sequence listing for the sequence recited on page 79 (containing nucleic acid sequences having more than 10 nucleic acids), the non-compliance rule is withdrawn.

Specification Informalities and objections withdrawn

4. In view of amendment to the specification in updating the status of all application, the specification informality is withdrawn.

5. In view of clarification of record along with exhibits A, B and C that the SEQ.ID.NO: 2580 and the corresponding amino acid sequence SEQ.ID.NO: 6352 are part of the sequences submitted under ATCC: 55998, the specification objection is withdrawn.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Claim Rejections - 35 USC 112, second paragraph withdrawn

6. In view of amendment to the claims, the rejection under 35 U.S.C. 112, second paragraph is withdrawn.

Claim Rejections - 35 U. S. C. § 102 withdrawn

7. In view of amendment to the claims and arguments of record, the rejection under 35 U.5.C. 102(e) as being clearly anticipated by Ohno et al, US Patent 5,770,375 is withdrawn.

Claim Rejections - 35 USC 112, first paragraph maintained

8. The written description rejection of claims 1-13 and 32 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

The specification teaches an isolated nucleic acid sequence as set forth in SEQ.ID.NO: 2580 (1008 nucleic acid sequence), an isolated nucleic acid (i.e., SEQ.ID.NO: 2580) encoding the *S.epidermidis* polypeptide comprising the amino acid sequence SEQ.ID.NO: 6352 (335 amino acid sequence). However, the specification does not disclose an isolated DNA sequence encoding a polypeptide comprising SEQ.ID.NO: 6352 and unlimited/ unknown sequences, isolated nucleic acid comprising SEQ.ID.NO: 2580 + unlimited/ unknown sequences, an isolated nucleic acid comprising a nucleotide sequence of at least 8 nucleotides that hybridizes under high stringency conditions to SEQ ID NO: 2580, an isolated nucleic acid comprising a nucleotide sequence, wherein the nucleotide sequence hybridizes under high stringency conditions to SEQ ID NO: 2580 or fragments (all these are viewed as fragments/variants) and said fragments/variants having a specific function. The specification does not disclose immunogenic composition for the treatment or prevention of *S.epidermidis* infection. Therefore, said fragments/variants or immunogenic composition for the treatment or prevention of *S.epidermidis* infection as claimed do not meet the guidelines on written description.

The specification fails to disclose any deletion or change in a polynucleotide sequence, SEQ.ID.NO: 2580 to obtain fragments/variants that could hybridizes to the sequence presented in the SEQ ID NO: 2580. The specification does not describe any use of said fragments/variants as claimed (comprising, open language) in identifying *S. epidermidis.* None of the above polypeptides meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116).

Thus, the specification fails to teach the fragments/variants of nucleic acid or immunogenic composition for the treatment or prevention of *S.epidermidis* infection and does not satisfy the written description guidelines because the claimed fragments/variants encoded by have not been disclosed in this application. In addition, an isolated nucleic acid comprising (open language) a sequence SEQ.ID.NO: 2580 plus unlimited and unknown nucleic acid would result in an unknown nucleic acid without sufficient structure and completely lacking identifying characteristics such as function. Thus, nucleic acid fragments/variants as claimed are broader than the SEQ.ID.NO: 2580 and do not appear to have sufficient structural characterization and lack any identifying characteristics (function). The specification fails to teach the structure or relevant identifying characteristics of said fragments/variants, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. Adequate

written description requires more than a mere statement that it is part of the invention and reference to a potential method for making it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Applicant's arguments 3/21/06 have been fully considered but they are not deemed to be persuasive.

Applicant states that examiner's interpretation of "comprising", "a polypeptide "and "a "nucleic acid" in the claims is incorrect because the term "comprising" is permissible under U.S. patent law and "comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added. Thus, the isolated nucleic acid of claim 1, for example, comprises a nucleotide sequence encoding an *S. epidermidis* polypeptide of SEQ ID NO: 6352, as well as additional elements which are not, and are not required to be specified. Further, applicant shows support for sequences encoding second polypeptide portions for generation of fusion proteins on pages 10 and 11, methods for identifying characteristics of the fragments/variants on page 62.

The examiner carefully reviewed the cited material of record and understands that the specification discloses an isolated nucleic acid comprising the nucleic acid sequence encoding an *S.epidermidis* polypeptide as set forth in the SEQ.ID.NO: 6352, an isolated nucleic acid sequence as set forth in SEQ.ID.NO: 2580 encoding an *S.epidermidis* polypeptide consisting of 12 contiguous nucleotide, a probe consisting of ten contiguous nucleotides of SEQ.ID.NO: 2580 an isolated nucleic acid sequence consisting of 10 nucleotides, said sequence hybridizes under high stringency conditions to SEQ.ID.NO: 2580. Applicant is aware recitation of open language "comprising" in the claims leaves the claims open to include essential and other elements. Therefore, essential fragments of said sequence plus unknown amino acids (other elements)

would result in a nucleotide sequence that is not the same as claimed sequence. Therefore, the examiner's interpretation of the claim language is correct and hence the rejection is maintained.

9. The scope of enablement rejection for claims 1-13 and 32 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

Claims 1-13 and 32 are under 35 U.5.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid sequence as set forth in SEQ.ID.NO: 2580 encoding the *S.epidermidis* polypeptide comprising the amino acid sequence as set forth in SEQ.ID.NO: 6352, an isolated nucleic acid sequence comprising the nucleic acid sequence SEQ.ID.NO: 2580 and an immunogenic composition comprising said isolated sequences nucleotide sequence SEQ.ID.NO: 2580, encoding the *S.epidermidis* polypeptide comprising the amino acid sequence as set forth in SEQ.ID.NO: 6352 does not reasonably provide enablement for an isolated nucleic acid or immunogenic composition for the treatment or prevention of *S.epidermidis* comprising a nucleotide sequence encoding a *S.epidermidis* polypeptide comprising SEQ ID NO: 6352, an isolated nucleic acid sequence comprising a nucleotide sequence encoding a *S.epidermidis* polypeptide or fragment thereof , wherein said nucleic acid is SEQ ID NO: 2580, an isolated nucleic acid comprising a nucleotide sequence of at least 8 nucleotides that hybridizes under high stringency conditions to SEQ ID NO: 2580 or an isolated nucleic acid comprising a nucleotide sequence , wherein the nucleotide sequence hybridizes under high stringency conditions to SEQ ID NO: 2580 or its complements (all these are viewed as fragments/variants) . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims have been discussed supra.

The specification fails to provide an enabling disclosure for the full scope of claimed nucleic acids as discussed above because it fails to provide any guidance regarding how to make and use said isolated nucleic acid or isolated nucleic acid encoding a polypeptide.

The instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is related to genomic cloning of *S.epidermidis* strain, 18972 in an expression vector. Several genomic nucleic acid sequences and the encoding polypeptides have been disclosed in the specification.

The state of the art indicates that *S.epidermidis (*gram positive bacteria*)* is a coagulase negative *Staphylococci (*CoNS*)* present in normal skin flora and is frequently isolated bacteria in the clinical laboratories (Wieser M, Int .J. Syst. Evol. Microbiol. 2000 May;50 Pt 3:1087-93). This bacterium is frequently associated with bacteremia and post catheterization infections and recognized as important nosocomial pathogen. However, identification of gram positive, coagulase negative *S.epidermidis* bacterial infection from other known species like *S.aureus* is still a problem and DNA based assays are still in the developmental stage only.

The current invention discloses an isolated nucleic acid comprising the nucleic acid sequence SEQ.ID.NO: 2580 and an isolated nucleic acid sequence encoding *S.epidermidis* polypeptide comprising the amino acid sequence SEQ.ID.NO: 6352. The specification fails to disclose how to make and use an isolated nucleic acid or immunogenic composition comprising a nucleotide sequence encoding a *S.epidermidis* polypeptide comprising SEQ ID NO: 6352, an isolated nucleic acid sequence comprising a nucleotide sequence encoding a *S.epidermidis* polypeptide or fragment thereof, wherein said nucleic acid is SEQ ID NO: 2580 or immunogenic composition. The specification lacks guidance how an isolated nucleic acid comprising a nucleotide sequence of at least 8 nucleotides plus other nucleic acid sequence would hybridize under high stringency conditions to SEQ ID NO: 2580 or an isolated nucleic acid comprising a nucleotide sequence, wherein the nucleotide sequence hybridizes under high stringency conditions to SEQ ID NO: 2580 or its complements (all these are viewed as fragments/variants). The specification provides no disclosure of said fragments/variants with a specific function. These fragments have not been shown to be positively identifying *S.epidermidis* infection.

These nucleic acid sequences are broadly claimed as an isolated DNA sequence encoding a polypeptide comprising SEQ.ID.NO: 6352 plus unlimited/ unknown sequences, isolated nucleic acid comprising SEQ.ID.NO: 2580 plus unlimited/ unknown sequences. However, the art in bacteriology teaches modifications in a protein for example, replacement of tyrosine 158 (Y158) to phenylalanine (Y158F) resulted in decrease in K_{cat} catalytic activity of InhA, the enoyl-ACP from *M.tuberculosis* (see abstract and tables 2-3 (Biochemistry 1999, Parikh et al, 38; 13623-13633). Further, modification of histidines with diethylpyrocarbonate has been shown to reduce the hemolytic activity of alpha-toxin (Infect Immun. 1994 May; 62(5): 1843-7) of *Staphylococcus aureus*. In addition, it is known that (see, Antimicrobial Agents and Chemotherapy, March 2001, p. 805-809, Vol. 45, No. 3) Sulfonamide resistance in *Streptococcus pneumoniae* is due to changes in the folP (*sulA*) gene coding for dihydropteroate synthase (DHPS). The emergence of Clarithromycin resistant *S.epidermidis* (Emerging Infectious Diseases 2005, Vol 11, (9) 1389-1393) infection in clinical patients indicates that resistant variants are developed. These references teach the changes made in the gene affect the function of the protein and leads to the development of drug resistant bacteria.

The specification fails to disclose nucleic acid fragments/variants/variants or polypeptide fragments/variants encoded by the nucleotide sequence of SEQ ID N0: 2580 and immunogenic composition for the treatment or prevention of *S.epidermidis* infection comprising a nucleotide sequence encoding a *S.epidermidis* polypeptide comprising SEQ ID NO: 6352 and a nucleotide sequence of SEQ ID N0: 2580 and said polypeptide fragments The specification fails to teach the critical protein residues involved in this function of the protein encoded by SEQ ID N0: 2580, such that the skilled artisan is provided no guidance to test, screen or make the nucleic acid sequence variants of SEQ ID N0: 2580 or encoding variants of polypeptide 6352.

It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases (for example, Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding enablement. Several publications as shown below document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. The following publications that support this unpredictability as well as noting certain

conserved sequences in limited specific cases: Gerhold et al. [BioEssays, Volume 18, Number 12, pages 973-981(1996)]; Wells et al. [Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; and Russell et al. [Journal of Molecular Biology, Volume 244, pages 332-350 (1994)]. One of skill in the art would be reduced to merely randomly altering nucleic acids, which would lead to unpredictable results regarding the functional activity of the protein.

Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted a priori and must be determined empirically on a case by case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis in proteins and they differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition. The specification has not taught which residues of the nucleotide sequence of SEQ ID N0: 2580 can be varied and still achieve a protein that is functional as claimed. Further, random insertions, deletions and changes to a nucleotide sequence do not provide guidance to make a related protein. The actual structure or other relevant identifying characteristics of each nucleic acid that encodes a variant protein can only be determined empirically by actually making every nucleic acid that encodes the recited variability (i.e. the substitutions, insertions or deletions as compared to SEQ ID N0: 2580) and testing each to determine whether it encodes a protein variant having function. If there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonable predict the complete structure of the claimed invention However, the specification fails to provide the function of the full-length protein and immunogenic composition for the prevention and treatment of *S.epidermidis* infection comprising said protein or its fragments.

Moreover, from the definition of Applicants' invention as set forth in the specification, it is unclear exactly what the composition of any protein will be if it is expressed by a nucleic acid which has the claimed fragments. For, example, if one nucleotide is deleted or inserted at a single place within the coding sequence, all the codons down stream of that insertion or deletion will be frame shifted. If that frame shift takes place near the 5' end of the gene, it is highly likely that the protein expressed will have little in common structurally or functionally with the protein encoded by the nucleic acid of SEQ ID N0: 2580. The specification fails to provide the protein disclosed as SEQ ID N0: 6352 encoded by the nucleic acid of SEQ ID N0: 2580, has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural nucleotide sequence which encodes it. There must be some nexus between the

structure of a nucleotide sequence and the structure of the protein encoded, and the function of that encoded protein. However, function cannot be predicted from the modification of the structure of the gene sequence or in this case the nucleotide sequence encoding the protein. The specification has not shown that, by modifying a reference sequence encoding a reference polypeptide as claimed, will automatically predict the production of a polypeptide for use in any assay. The specification does not set forth the general tolerance to substitutions, where substitutions could be made to obtain equivalent protein variant. Since, the specification lacks support for any variant which has the ability to function as claimed, it is not enabled for this broad fragment/variant language because it fails to enable the skilled artisan to envision the detailed chemical structure of the polypeptide for use. In view of the lack of support for protein fragment/variant encoded by the nucleic acid fragment/variant of SEQ ID N0: 2580 that functions equivalently as claimed full length protein and the corresponding nucleic acid sequence, the lack of enabling description of how to make functionally equivalent polypeptide fragment/variant, the unpredictability associated with making and using the myriad of functionally equivalent fragment/variant encompassed in the scope of the claims as set forth above, the lack of teaching for variation of the nucleic acid for routine experimentation, the lack of an assay to screen for fragment/variant, lack of working examples commensurate in scope with the instant claims, the skilled artisan would be forced into undue experimentation to practice (i.e. make and use) the broadly claimed nucleic acid fragment/variant of the invention.

Applicant's arguments 3/21/06 have been fully considered but they are not deemed to be persuasive.

Applicant states that (a) contrary to the arguments of the examiner, the specification provides the definition of "fragment" (for example, page 24, lines 7-14) and methods for making fragments (for example, page 37, line 1 through page 39, line 5, describing methods by the function of a gene can be ascertained). Applicant also states that (b) claims I -4 are improperly rejected under this section as claim 1 does not suffer from the alleged deficiencies.

The examiner disagrees with the applicant because (a) while fragments **consisting** of short peptides are known, widely available and are used in the art but an isolated nucleic acid **comprising** a nucleotide sequence encoding an S.*epidermidis* polypeptide or a fragment as claimed have not been supported by the specification. Further (b) recitation of an open claim language "comprising" does not indicate that applicant is claiming an isolated nucleic acid comprising the nucleotide sequence encoding the *S.epidermidis* polypeptide SEQ.ID.NO: 6352 but appears to be claiming something different than the recited sequence. Further, recitation of

"an S.*epidermidis* polypeptide of " indicates that less than the full-length peptide is being claimed. Therefore, for the reasons as set forth above, claims 1-4 are properly rejected under this statue.

Claim Rejections - 35 U. S. C. § 102 maintained

10. The rejection of claims 1, 5, 9, 10 and 32 under 35 U.5.C. 102(b) as being clearly anticipated by Goh et al Clin Microbiol. 1996 Apr; 34(4): 818-23 is maintained for the same reasons as set forth in the previous office action.

Goh et al disclose an isolated nucleic acid molecule amplified by PCR, encoding a portion of the 60-kDa protein (see table 1, figure 1 and 2) from *Staphylococcus epidermidis* using a set of universal degenerate primers, a 600-bp oligomer. However, when used as a DNA probe, the 600-bp PCR product generated from S. epidermidis failed to cross-hybridize under high-stringency conditions with the genomic DNA of S. aureus and vice versa. It is inherent that the PCR product as shown in table 1. Figure 1 and 2 contains the claimed isolated nucleic acid SEQ.ID.NO: 2580 and encodes polypeptide SEQ.ID.NO: 6532 because the PCR product is specific for *S.epidermidis* and the 600 base pair PCR product (nucleic acid product) appears to be containing the claimed nucleic acid that encodes the polypeptide having less than 60kD protein (i.e., claimed polypeptide is approximately 40kD). In the absence of evidence to the contrary the disclosed prior art PCR product (nucleic acid) would inherently contains the claimed nucleic acid as the use of PCR coupled with restriction endonuclease analysis of PCR product has proven to be sensitive and specific in the art.
product.

Applicant's arguments 3/21/06 have been fully considered but they are not deemed to be persuasive.

Applicant states (a) the limitation "comprising" refers to isolated nucleic acid and not to the nucleotide sequence encoding the polypeptide, (b) Goh's nucleotide sequences is from *SE* 9759, not SE 8972 (c) Goh' s S. *epidermidis* strain is a different strain that of Applicant (d) the nucleotide sequence of the genome is not publicly available (Exhibit E, F).

The examiner is not able to understand what applicant meant by "comprising" refers to isolated nucleic acid and not to the nucleotide sequence encoding the polypeptide, However, the claims are correctly rejected (a) over the prior art nucleic acid (PCR product) comprising nucleotide encoding 60-kDa protein (see table 1, figure 1 and 2) from *Staphylococcus*

epidermidis is an isolated nucleic acid (PCR product) that comprises nucleotide sequence that encodes a *S.epidermidis* polypeptide. Therefore, the examiner's rejection is appropriate over the prior art isolated nucleic acid (PCR product). Further. Applicant's arguments of b and c about the limitations "different strain" and " *S. epidermidis* SE 8972 " etc are not set forth in the claims. (d) The examiner did not reject the claims over genome because rejected the claims over isolated nucleic acid, PCR product.

New Rejection Based on Amendment

11. Claim 5 is rejected as being vague and confusing because it is not clear how an isolated nucleic acid fragment having 12 contiguous nucleotides encode a polypeptide?

Remarks

12. Claims 33 and 34 are free of prior art and appear to be allowable.

Claims 1-13 and 32 stand rejected.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action

14. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives

transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER